NOV - 4 2011 K112408

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510(k) Summary

Contact Person: Helen Landicho

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Summary prepared August 15, 2011

510(k) number:	
Name of the device:	Poly-Chem® 90 ISE Module
Device common name:	Ion selective electrode module; test for sodium, potassium, chloride
Product code:	JGS, CEM, CGZ
Regulation number:	862.1665, 862.1600, 862.1170
Classification:	Class II
Predicate Device:	Randox RX Daytona ISE Module
Device common name:	Ion selective electrode module; test for sodium, potassium, chloride
510(k) number:	K024014
Product code:	JGS, CEM, CGZ
Regulation number:	862.1665, 862.1600, 862.1170
Classification:	Class II

Device Description: Poly-Chem 90 ISE Module is for the quantitative in vitro measurement of the level of sodium, potassium and chloride in human serum on the Poly-Chem 90 clinical chemistry analyzer. The ISE module measures sodium, potassium and chloride using ion selective electrode technology.

Intended use: Poly-Chem 90 ISE Module is for the quantitative in vitro measurement of the level of sodium, potassium and chloride in human serum on the Poly-Chem 90 clinical chemistry analyzer. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the

diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Similarities and Differences with Predicate Device

Similarities and Differences ISE Module		
Item	Poly-Chem 90 ISE Module	RX Daytona ISE Module
Intended Use	For the quantitative in vitro measurement of the level of sodium, potassium, and chloride in human serum on the Poly-Chem 90 analyzer.	For the quantitative in vitro measurement of the level of sodium, potassium, and chloride in human serum, plasma, and urine on the RX Daytona analyzer.
Indications for Use	Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.	Same
Sample type	Serum	Serum, plasma, urine
Methodology	Ion selective electrode	Same
Precision (Na)	Intraassay: %CV from 0.06% to 0.27% Interassay: %CV from 0.28% to 0.94% Samples from 82.9 to 173 mmol/L	Intraassay: %CV from 0.52% to 0.75% Interassay: %CV from 0.90% to 1.28% Samples from 136.9 to 154 mmol/L
Precision (K)	Intraassay: %CV from 0.14% to 0.33% Interassay: %CV from 0.43% to 1.08% Samples from 2.41 to 7.3 mmol/L	Intraassay: %CV from 0.39% to 0.54% Interassay: %CV from 1.43% to 1.63% Samples from 3.96 to 5.96 mmol/L

Similarities and Differences ISE Module		
Item	Poly-Chem 90 ISE Module	RX Daytona ISE Module
Precision (Cl)	Intraassay: %CV from 0.08% to 0.54% Interassay: %CV from 0.33% to 1.20% Samples from 53.8 to 134 mmol/L	Intraassay: %CV from 0.53% to 0.82% Interassay: %CV from 0.97% to 1.02% Samples from 98.1 to 114 mmol/L
Measuring range	33.5 – 191.6 mmol/L (Na) 0.5 – 9.98 mmol/L (K) 41.0 – 169.8 mmol/L (Cl)	20 – 200 mmol/L (Na) 0.2 – 20 mmol/L (K) 25 – 200 mmol/L (Cl)
Comparison with Predicate (Na)	$y = 1.04x - 5.06$, $r = 0.9929$; 63 samples from 56.0 – 189.0 mmol/L	$y = 0.91x + 8.60$, $r^2 = 0.99$ N = 91
Comparison with Predicate (K)	$y = 0.99x + 0.02$, $r = 0.9982$; 74 samples from 1.39 – 9.13 mmol/L	$y = 0.97x + 0.09$, $r^2 = 0.99$ N = 73
Comparison with Predicate (Cl)	$y = 1.01x - 1.64$, $r = 0.9985$; 74 samples from 49.0 – 166.0mmol/L	$y = 0.98x - 0.27$, $r^2 = 0.99$ N = 84
Expected values	136 – 146 mmol/L (Na) 3.5 – 5.1 mmol/L (K) 97 – 107 mmol/L (Cl)	Same
Calibration	Medica Calibrator A and Calibrator B	Same
Analyzer	Poly-Chem 90	RX Daytona

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Summary of performance testing

To demonstrate substantial equivalence, performance characteristics that were tested included precision, linearity, sensitivity, interferences, and method comparison. Results of this testing are summarized below. The results indicate that the Poly-Chem 90 ISE Module is substantially equivalent to currently marketed Sodium, Potassium, and Chloride test systems.

Precision

				Within run		Between run	
	Sample	Instrument	Mean	SD	CV	SD	CV
Sodium	1	1	83.54	0.222	0.27	0.781	0.94
		2	82.91	0.101	0.12	0.589	0.71
	2	1	139.05	0.254	0.18	0.783	0.56
		2	139.70	0.160	0.11	0.646	0.46
	3	1	172.03	0.285	0.17	0.768	0.45
		2	172.95	0.099	0.06	0.481	0.28
Potassium	1	1	2.43	0.008	0.33	0.026	1.08
		2	2.41	0.007	0.29	0.022	0.90
	2	1	3.91	0.007	0.18	0.019	0.49
		2	3.89	0.007	0.17	0.017	0.43
	3	1	7.3	0.012	0.16	0.046	0.63
		2	7.3	0.010	0.14	0.049	0.68
Chloride	1	1	54.4	0.29	0.54	0.66	1.20
		2	53.8	0.17	0.32	0.53	0.98
	2	1	101.0	0.15	0.14	0.35	0.34
		2	101.0	0.08	0.08	0.37	0.36
	3	1	134.0	0.15	0.11	0.45	0.34
		2	133.8	0.13	0.10	0.44	0.33

Linearity of the test

	Range	**Slope (95% CI)**	**Intercept (95% CI)**	r^2
Sodium	30.4 – 191.6	0.99 (0.97 to 1.00)	0.09 (-1.92 to 2.11)	0.9989
Potassium	1.09 – 9.98	0.98 (0.98 to 0.99)	0.17 (0.13 to 0.21)	0.9998
Chloride	31.3 – 169.8	1.02 (1.00 to 1.04)	-5.35 (-7.62 to -3.07)	0.9989

Sensitivity

Test	Limit of Blank	Limit of Detection	Limit of Quantitiation (10% CV)
Sodium	32.4 mmol/L	33.5 mmol/L	32.5 mmol/L
Potassium	0.35 mmol/L	0.393 mmol/L	0.5 mmol/L
Chloride	40.2 mmol/L	41.0 mmol/L	40.8 mmol/L

Interference

Test	Hemoglobin	Bilirubin	Triglyceride
Sodium	800 mg/dL	7.5 mg/dL	549 mg/dL
Potassium	800 mg/dL	25 mg/dL	663 mg/dL
Chloride	800 mg/dL	25 mg/dL	549 mg/dL

Comparison with predicate device

Test	n	Range of samples	Slope (95% CI)	Intercept (95% CI)	r
Sodium	63	56.0 – 189.0	1.04 (1.00 to 1.08)	-5.06 (-11.47 to -0.30)	0.9929
Potassium	74	1.39 – 9.13	0.99 (0.97 to 1.01)	0.02 (-0.04 to 0.11)	0.9982
Chloride	74	49.0 – 166.0	1.01 (1.00 to 1.03)	-1.64 (-2.91 to -0.10)	0.9985

Conclusions

Poly-Chem 90 ISE Module is substantially equivalent to currently marketed Sodium, Potassium, and Chloride test systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 04 2011

Polymedco, Inc.
c/o Helen Landicho
Vice President of Regulatory Affairs
510 Furnace Dock Rd.,
Cortlandt Manor, NY 10567

Re: k112408
Trade/Device Name: Poly-Chem 90 ISE Module
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium test system.
Regulatory Class: II
Product Code: CEM, CGZ, JGS
Dated: August 16, 2011
Received: August 22, 2011

Dear Ms. Landicho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112408

Device Name: Poly-Chem 90 ISE Module

Indications For Use:

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Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112408